

Part III – Administrative, Procedural, and Miscellaneous

Branded Prescription Drug Sales

Notice 2011-9

Purpose

This notice modifies, restates, and supersedes Notice 2010-71, 2010-50 I.R.B. 822, which provides guidance on the annual fee imposed by section 9008 of the Affordable Care Act on certain manufacturers and importers (covered entities) of branded prescription drugs. The modifications reflected in this notice affect Part I - Information Requested from Covered Entities, Part II – Preliminary Fee Calculation for 2011, and Part III – Request for Comments. All other sections of Notice 2010-71 are restated in this notice without change.

Modifications Made to Notice 2010-71

Notice 2010-71, Part I - Information Requested from Covered Entities, asks covered entities to submit five general items of information on Form 8947, Report of Branded Prescription Drug Information. The Treasury Department and the IRS received a number of comments on the information requested on Form 8947. In response to these comments, this notice makes the following changes to the section on Information Requested from Covered Entities:

- Item 1 (controlled group). The instructions to Form 8947 provided that each designated entity should list information on “all” members of its controlled group. This item is modified to clarify that information is requested for only those members of the controlled group that are manufacturers and importers with gross receipts from the sale of a branded prescription drug(s) to a specified government program(s).
- Item 3 (orphan drugs). Notice 2010-71 provided for reporting of each orphan drug for which a covered entity was allowed a section 45C credit. In response to comments, this item is modified to provide that for purposes of section 9003(e)(3), the credit is considered “allowed” for any particular drug if any person claimed the credit. Thus, the section 45C credit is considered to be allowed if any entity claimed the credit even if that entity was not part of the covered entity at the time the credit was claimed.
- Item 4 (Medicare Part D rebates). Notice 2010-71 provided for reporting of rebates for drug sales as taken into account on a covered entity’s tax return. Commentators indicated that pharmaceutical manufacturers generally compile rebate information at an aggregate entity level for tax purposes, rather than at the

drug product level. In response to these comments, this item is revised to provide that rebates should be reported for drugs dispensed in the 2009 sales year if the rebates are paid before Form 8947 is filed.

- Item 5 (Medicaid rebates). This item is also revised in response to the comments about the difficulty of reporting rebates as taken into account on the covered entity's tax return. This item is revised to require reporting of rebates invoiced by states for drugs reimbursed by states in the 2009 sales year and paid before Form 8947 is filed.
- Reporting of rebate information. This notice provides that rebate information will be taken into account in calculating a covered entity's annual fee for 2011 only if it is reported on a timely filed Form 8947.

Notice 2010-71, Part II – Preliminary Fee Calculation for 2011, provides the due date for filing Form 8947 and a time schedule for notification of the preliminary fee calculation for 2011. Commentators requested additional time to file Form 8947. In response to these comments, the due date for filing Form 8947 is deferred to February 11, 2011, and the remaining time schedule for preparing the preliminary fee calculation has been revised accordingly.

Notice 2010-71, Part III – Request for Comments, is revised to defer the deadline for submitting comments to June 15, 2011.

Restatement of Notice 2010-71, as modified by this notice

This notice provides guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)). All references in this notice to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA.

Part I of this notice describes a proposed methodology for calculating the section 9008 fee. Part II of this notice describes how the Internal Revenue Service (IRS) will use this proposed methodology to provide each covered entity with a preliminary 2011 fee calculation. The IRS and Treasury Department intend that a covered entity's preliminary fee calculation for 2011 will serve as a basis for comments by the covered entity on the proposed methodology. Part III of this notice solicits public comments on all aspects of the notice.

Part I – Proposed Methodology for Calculating the Fee

Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be allocated among covered entities with aggregate branded prescription drug sales of over \$5 million to specified government programs or pursuant to coverage under such programs. Section 9008(e)(2) provides that “branded prescription drug” means (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or (ii) any biological product the license for which was submitted under section 351(a) of the

Public Health Service Act (42 U.S.C. 262(a)). The specified government programs are the Medicare Part B program, the Medicare Part D program, the Medicaid program, any program under which branded prescription drugs are procured by the Department of Veterans Affairs, any program under which branded prescription drugs are procured by the Department of Defense, and the TRICARE retail pharmacy program (collectively, the Programs). The applicable fee amount is allocated among the covered entities using a formula specified in section 9008(b) based on sales to the Programs, which sales data is to be provided by the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS), the Department of Veterans Affairs (VA), and the Department of Defense (DOD) (collectively, the Agencies).

There are two years relevant to the calculation of the section 9008 fee – the calendar year in which the fee must be paid (herein referred to as the fee year) and the calendar year of the branded prescription drug sales, which will be used to determine the amount of the fee (herein referred to as the sales year). As discussed more fully below, the IRS and Treasury Department are proposing to use the second calendar year proceeding the fee year as the sales year for purposes of calculating the section 9008 fee. An adjustment amount will also be calculated as discussed below.

Definition of Covered Entity

Section 9008(a) imposes the fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs. Section 9008(d)(1) defines a covered entity as “any manufacturer or importer with gross receipts from branded prescription drug sales.” For purposes of section 9008(a), a manufacturer or importer is the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug. The NDC is an identifier assigned by the Food and Drug Administration (FDA) to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

Section 9008(d)(2) provides a controlled group rule under which all persons treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code (Code) shall be treated as a single covered entity. For this purpose, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). This controlled group rule will be applied as of the end of the day on December 31 of the sales year. All persons treated as a single employer under section 9008(d)(2) are jointly and severally liable for the fee. See section 9008(d)(3).

In the case of a controlled group that is treated as a single covered entity under section 9008(d)(2), the controlled group must identify a single person as the “designated entity” that may act for the controlled group with respect to the section 9008 fee. If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that filed a consolidated return for federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. In all other situations, the controlled group must select a person as the designated entity on Form 8947, Report of Branded Prescription Drug Information¹ (discussed further below), which is signed by

¹ The Office of Management and Budget approved Form 8947 under control number 1545-2192.

the designated entity under penalties of perjury, stating that all the manufacturers or importers of branded prescription drugs who are members of the covered entity have consented to the selection of the designated entity.

Sales Taken Into Account

Section 9008(b) provides that the annual fee for each covered entity is calculated by determining the ratio of (i) the covered entity's branded prescription drug sales taken into account during the preceding calendar year to (ii) the aggregate branded prescription drug sales taken into account for all covered entities during the same year, and applying this ratio to the applicable amount as specified in the statute. "Sales taken into account" means sales exclusive of certain orphan drugs and after application of the percentage adjustment table in section 9008(b)(2). Section 9008(b)(1) provides that the calculation of the fee in any given year is based on branded prescription drug sales in the immediately preceding calendar year.

Section 9008(b)(3) provides that the Secretary of the Treasury shall determine the amount of each covered entity's fee. In determining that amount, the Secretary may rely on reports submitted by the Agencies and any other source of information. Section 9008(i) also provides the Secretary with regulatory authority to carry out the purposes of the statute.

The IRS and Treasury Department have determined that, although the DOD and VA are expected to have complete data on branded prescription drug sales for the calendar year immediately preceding the fee year within the time frame necessary to administer the fee, CMS is not expected to have comparable data because it cannot complete its data processing within the necessary time frame. Accordingly, the IRS and Treasury Department will calculate the fee based on the branded prescription drug sales data provided by the Agencies for the second calendar year preceding the fee year. Because the use of the second preceding year, rather than the immediately preceding year, as the sales year may affect the amount of the fee paid by any particular covered entity, the fee due in every year after 2011 will include an adjustment amount.

Adjustment Methodology

An adjustment amount will be calculated for each NDC and will be added or subtracted, as appropriate, to the fee otherwise payable by the covered entity responsible for the NDC in the fee year in which the adjustment is calculated. The adjustment amount added or subtracted to the amount payable in a fee year will reflect the difference between the fee determined for the NDC in the immediately prior fee year, using data from the second calendar year preceding that fee year, and what the fee for that NDC would have been for the immediately prior fee year using data from the calendar year immediately preceding that prior fee year. For example, the amount due from a covered entity in the 2012 fee year will include an adjustment amount for each NDC for which the covered entity is responsible in 2012 equal to the difference between the 2011 fee associated with that NDC using 2009 data, and what the 2011 fee for that NDC would have been using 2010 data.

To calculate the adjustment amount for an NDC, the IRS will first determine two ratios: one based on data from the second preceding calendar year; and the other based on data from the third preceding calendar year. In both cases, the numerator of the ratio is the sales taken into account for the particular NDC during the relevant

calendar year, and the denominator of the ratio is aggregate branded prescription drug sales taken into account for all NDCs during the relevant calendar year. For each NDC, the IRS will then take the difference between the ratio using second preceding year data and the ratio using third preceding year data and multiply that amount by the applicable amount of the fee for the relevant fee year, as set forth in section 9008(b)(4), to determine an adjustment for the NDC. The adjustment amount for any particular NDC will then be added to, or subtracted from, as appropriate, the amount of the fee otherwise payable by the covered entity associated with the NDC for the fee year in which the adjustment amount is calculated.

For example, in 2012 the fee payable by each covered entity will consist of two components. First, the applicable amount for 2012 will be allocated to the covered entities based on sales data for 2010 (i.e., the second preceding calendar year). Second, an adjustment amount will be calculated in 2012 for each NDC with respect to the 2011 fee year, by multiplying (i) the difference between the sales ratio determined using 2010 data and the sales ratio determined using 2009 data by (ii) the applicable amount of the fee for 2011. The adjustment amount for each NDC will then be added to, or subtracted from, as appropriate, the fee otherwise payable in 2012 by the covered entity associated with the NDC for the 2012 fee year.

The adjustment amount is applied only with respect to the amount of the fee otherwise payable by the relevant covered entity in the year in which the adjustment is calculated, and is not a refund, credit, or recalculation of a fee payable by any covered entity in any preceding fee year. In any given fee year, the amount assessed by the IRS will be based on data provided to it by the Agencies. The IRS does not intend to recalculate either the fee allocations or the adjustment amounts based on data that becomes available after those amounts are assessed.

Information Requested from Covered Entities

Annually, each covered entity should submit a Form 8947 and provide the information specified by the form and instructions. The designated entity for a covered entity described in section 9008(d)(2) submits a single form for the covered entity. A covered entity should submit a completed Form 8947 by December 15 of each year unless an alternative date is prescribed by the form or instructions. The Form 8947 information is return information subject to the confidentiality protections of section 6103. The IRS will take into account the rebate information in calculating a covered entity's annual fee for 2011 only if the rebate information is reported in accordance with items 4 and 5 below on a timely filed Form 8947. Form 8947 is available at <http://www.irs.gov>.

Form 8947 solicits the following information from each covered entity:

1. For a single-person covered entity, the covered entity's name, address, and employer identification number. For a covered entity described in section 9008(d)(2), the name, address, and employer identification number of the designated entity and each manufacturer or importer with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the programs) that was included in the covered entity as of the end of the day on December 31 of the sales year.

Part I of Form 8947 instructions are revised by this notice to provide that each designated entity should list the name, address, and employer identification number of

itself and each manufacturer or importer with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the programs) that was included in the covered entity as of the end of the day on December 31 of the sales year.

2. All of the NDCs for branded prescription drugs in which the covered entity is identified in the labeler code as of the end of the day on December 31 of the sales year. For a covered entity described in section 9008(d)(2), this includes all NDCs in which a member of the covered entity is identified in the labeler code as of the end of the day on December 31 of the sales year.

3. The brand name and NDC for each orphan drug for which a credit was allowed for any taxable year under section 45C of the Code. For purposes of section 9008(e)(3), the credit was “allowed” for any particular drug if any person claimed the credit and there has not been a final assessment or a court order disallowing the full credit taken for the drug. In addition, even if the credit has been allowed, a covered entity must not report an NDC for an orphan drug for any sales year following the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed.

4. The rebates for each NDC paid for the sales year by the covered entity to Medicare Part D plans with respect to sales occurring in that sales year. For this purpose, report rebates paid for drugs dispensed in the 2009 sales year if paid before Form 8947 is filed. This information is needed for the 2009 sales year because, at this time, CMS does not have rebate data on branded prescription drug sales by NDC. However, starting in 2011, CMS is planning to collect this rebate information by NDC for the 2010 and subsequent sales years. It is therefore possible that covered entities will not report this rebate information for years following 2009.

5. The state supplemental rebates for each NDC paid in the sales year by the covered entity with respect to sales under Medicaid occurring in that sales year. For this purpose, report rebates invoiced by states for drugs reimbursed by states in the 2009 sales year and paid before Form 8947 is filed. This information is needed because Medicaid data will not include state supplemental rebates.

Information Provided by the Agencies

The IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947. Appropriate due diligence will be performed to check for potential oversights. For example, the IRS may use information published by the FDA identifying drugs for which applications were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. The IRS will provide the Agencies with the compiled list of branded prescription drugs.

For each year in which the fee is due, the Agencies will provide data to the IRS on the branded prescription drug sales during the sales year by Program and NDC. The calculation methodology for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, are described below.

1. Medicare Part D. Section 9008 requires CMS to report the product of the per-unit ingredient cost reported by Part D sponsors (net of any per-unit rebate or other price concessions) and the number of units for each branded prescription drug. CMS currently collects prescription level encounter data from Part D sponsors on the

Prescription Drug Event (PDE) records. On the PDE records, Part D sponsors report the NDC, as well as the ingredient cost, dispensing fee, sales tax, and units. CMS will aggregate the ingredient cost reported in the “Ingredient Cost Paid” field and the units reported in the “Quantity Dispensed” field of the PDE records for Part D covered drugs. These amounts will be aggregated at the NDC level for each sales year. Only PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and have been approved for inclusion in the Part D payment reconciliation will be included.

2. Medicare Part B. First, for Healthcare Common Procedure Coding System (HCPCS) codes that consist solely and exclusively of branded prescription drugs (as identified by their respective NDCs) manufactured by a single entity, CMS will provide the total Medicare-allowed charges for the HCPCS code for the appropriate sales year.

Second, for HCPCS codes consisting of a mixture of branded prescription drugs made by different manufacturers or a mixture of branded prescription and generic drugs, CMS will determine: (i) the total Medicare-allowed charges for the HCPCS code for the appropriate sales year; (ii) the entities engaged in manufacturing each NDC assigned to the HCPCS code; and (iii) those entities (if any) that are manufacturing branded prescription drugs. CMS will then: (i) estimate the amount of Medicare-allowed charges for each manufacturer by applying the utilization percentage attributed to each manufacturer as determined under the Medicare Part B Program using manufacturer reported Average Sales Price sales data; (ii) multiply that percentage by the Medicare-allowed charge for that HCPCS code; and (iii) assign the result to each manufacturer within that HCPCS code.

Third, for the remainder of HCPCS codes that consist of multiple branded prescription drugs (as identified by their respective NDCs) manufactured by multiple entities that cannot be reliably calculated using the two methods above, CMS will determine: (i) the total Medicare-allowed charges for the HCPCS code for the appropriate sales year; (ii) the entities engaged in manufacturing each NDC assigned to the HCPCS code; and (iii) those entities (if any) that are manufacturing branded prescription drugs. CMS will then: (i) estimate the amount of Medicare-allowed charges for each manufacturer by applying the utilization percentage attributed to each manufacturer as determined under the Medicare Part D Program; (ii) multiply that percentage by the Medicare-allowed charge for that HCPCS code; and (iii) assign the result to each manufacturer within that HCPCS code.

Thus, the amounts attributed to branded prescription drugs within the HCPCS code will be estimated. CMS will calculate the sum of these components to arrive at an estimate of Medicare Part B spending on branded prescription drugs for each manufacturer.

3. Medicaid. The branded prescription drug sales for Medicaid may be determined as the per-unit Average Manufacturer Price less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers. This data would be based on the data reported to Medicaid by covered entities and the states. CMS does not currently intend to reduce this calculation for state supplemental rebates.

4. Department of Veterans Affairs. VA will provide, by NDC, the total amount paid for each branded prescription drug procured by the VA for its beneficiaries. The

basis of this information will be national procurement data reported by VA's Pharmaceutical Prime Vendor to the VA Pharmacy Benefits Management Service and National Acquisition Center. This information will not include procurement data that resides exclusively at the individual medical treatment facility level.

5. Department of Defense. The DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates) for each branded prescription drug procured by DOD. TRICARE Management Activity will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of refunds or rebates) for each branded prescription drug procured by DOD through the TRICARE Retail Pharmacy Program.

Fee calculation

After receiving data from the Agencies and information from the covered entities, the IRS will calculate each covered entity's branded prescription drug sales for each Program by NDC. A covered entity's branded prescription drug sales for each Program will equal (i) the sum of all the covered entity's branded prescription drug sales reported by the Program, less (ii) the sum of all branded prescription drug sales reported by the Program for each NDC for which the covered entity has appropriately claimed the orphan drug exclusion, less (iii) the sum of rebates reported by the covered entity on Form 8947 for the sales year.

After calculating the branded prescription drug sales for each Program, the IRS will calculate each covered entity's branded prescription drug sales taken into account for purposes of the ratio set forth in section 9008(b)(1). A covered entity's branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A) will equal the sum of the covered entity's branded prescription drug sales for all Programs reduced by the appropriate percentages set forth in section 9008(b)(2). The IRS will then calculate the aggregate branded prescription drug sales of all covered entities taken into account for purposes of section 9008(b)(1)(B), which is the sum of all the covered entities branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A).

To determine each covered entity's fee, the IRS will divide each covered entity's branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A) by the aggregate branded prescription drug sales of all covered entities taken into account for purposes of section 9008(b)(1)(B) and multiply that fraction by the applicable amount for the appropriate year as set forth in section 9008(b)(4).

Part II – Preliminary Fee Calculation for 2011

The IRS will use the proposed methodology described in Part I to provide each covered entity with a preliminary 2011 fee calculation. The notification of the preliminary fee calculation will include the following: (1) the covered entity's fee; (2) the covered entity's branded prescription drug sales, by NDC, for each Program; (3) the covered entity's branded prescription drug sales taken into account after application of section 9008(a)(2); and (4) the aggregate branded prescription drug sales taken into account for all covered entities.

To facilitate the preliminary 2011 fee calculation, Form 8947 should be submitted to the IRS by February 11, 2011. From the data on the Forms 8947, the IRS will

compile a list of NDCs and provide that list to the Agencies as soon as the data has been processed. The IRS will use the data submitted on the Forms 8947 and the sales data provided by the Agencies to calculate the preliminary fee and will send to each covered entity notification of its preliminary fee calculation by May 16, 2011.

If the IRS and Treasury Department subsequently promulgate regulations that modify the methodology for calculating each covered entity's fee, the modified methodology will be adopted in determining the final fee amount for each covered entity for 2011. Thus, if the methodology changes, the amount of the final fee for 2011 may vary from the preliminary fee calculation. The IRS will send the final fee calculation to each covered entity by August 15, 2011.

Part III – Request for comments

The IRS and Treasury Department request comments on the procedures described in this notice for consideration when promulgating regulations setting forth procedures for 2011 and the following years. The deadline for submission of comments is June 15, 2011. This date will give covered entities the opportunity to consider the information received in their preliminary fee calculation when providing comments. All materials submitted will be available for public inspection and copying. Written comments should be submitted to: Internal Revenue Service, CC:PA:LPD:PR (Notice 2011-9), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2011-9), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Comments may be transmitted electronically via the following e-mail address: Notice.Comments@irs.counsel.treas.gov. Please include "Notice 2011-9" in the subject line of any electronic communications.

Effect on Other Documents

Notice 2010-71 is modified and superseded.

Drafting Information

The principal author of this notice is Celia A. Gabrysh of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice contact Celia A. Gabrysh on (202) 622-3130 (not a toll-free call). For further information regarding Form 8947 contact Lou Milano on (908) 301-2118 (not a toll-free call).